Citation:

Wien MA, Sabate JM, Ikle DN, Cole SE, Kandeel FR. Almonds vs. complex carbohydrates in a weight reduction program. *Int J Obes Relat Metab Disord.* 2003; 27(11): 1,365-1,372. Erratum in: *Int J Obes Relat Metab Disord.* 2004 Mar; 28 (3): 459.

PubMed ID: 14574348

Study Design:

Randomized trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

Evaluate the effect of an almond-enriched or complex carbohydrate-enriched formula-based low-calorie diet on anthropometric, body composition and metabolic parameters in a weight reduction program.

Inclusion Criteria:

- In the outpatient pool entering into the 24-week Diabetes and Cardiovascular Risk Reduction Program
  - Requires medical diagnosis that can be improved by weight reduction
  - 18 years or older
  - BMI>=25kg/m^2.

Exclusion Criteria:

- Use of lipid-lowering medications
- Women receiving hormone replacement therapy.

Description of Study Protocol:

Recruitment

Subjects recruited from the pool of outpatient participants entering into the Diabetes and Cardiovascular Risk Reduction program (i.e., 24-week medically-supervised weight reduction program at City of Hope National Medical Center).

Design

Randomized trial.

Subjects randomized (using Random Number Generation software) to the almond group or complex CHO group, stratified by gender and physician documented presence or absence of Type 2 diabetes.

Intervention

Two-week run-in period

No intervention other than a multivitamin or mineral supplement.

24-week intervention

Formula-based low-calorie diet (LCD; Health Management Resources 70 Plus, a protein-sparing formulation) supplemented with either one) 84 grams per day almonds or two) self-selected complex carbohydrates (equivalent in calories to 84g almonds) and two teaspoons of safflower oil per day.

	Almond	Complex CHO
Energy (kcal)	1,012	1,015
Protein (percentage of energy)	29	29
Carbohydrates (percentage of energy)	32	53
Fat (percentage of energy)	39	18
Saturated fatty acids	3	3
Monounsaturated fatty acids	25	5
Polyunsaturated fatty acids	11	10
Cholesterol (mg)	4	4
Dietary fiber (g)	20	32

Table. *Nutrient Composition of Intervention Diets.*

Note. Diet composition balanced on calories, protein, cholesterol, saturated fat.

Both groups: Instructed to mix powder according to package and consume HMR vitamin or mineral supplements two times per day. Advised to refrain from exercise during first four weeks and encouraged to walk 20-30 minutes, three to five times per week afterward.

Almond group: Pre-packaged whole, unblanched almonds given weekly to subjects. Instructed to consume almonds at same time each day.

Complex CHO group: Instructed how to self-select combination of complex CHO each day from a food list that was equivalent in calories to 84 grams of almonds, plus consume two teaspoons of safflower oil per day.

Statistical Analysis

- Two-sided unpaired T-tests were used to examine baseline characteristics. A mixed model with an autoregressive covariance structure of lag?one was used to test all hypotheses.
- All percentage change values presented are least-squares means estimated from mixed models
- The effect of each treatment on each end-point over time was plotted as the least-squares mean and 95% CI by treatment group over time for each end-point
- Models were adjusted for baseline measurements and all time points were included in the analysis
- Results are presented based on intent-to-treat analysis.

Compliance Assessment

Method: Subjects asked to maintain daily food and exercise records in program log books. Met weekly with R.D. face-to-face to review records and obtain feedback.

Excessive deviation from study protocol defined as failure to stay within 25% of weekly prescribed

calories and minutes of activity. Prompted additional individualized sessions with program psychologist or R.D.

Data Collection Summary:

Timing of Measurements

- 24-consecutive weekly clinical assessments (weight, BP, heart rate, ketone levels)
- Plasma lipids, insulin, glucose at baseline (week zero) and weeks eight, 16 and 24
- Satiety, palatability, and texture of diet at weeks eight, 16 and 24
- Waist circumference and bio-electrical impedance at week zero and 24.

Dependent Variables

- Plasma lipids (TC, HDL-C, LDL-C, Tg); venous blood collected after overnight fast; analyzed using the CDCs certified Lipid Research Clinics Protocol for TC, Tg, and HDL-C after dextran sulfate-magnesium chloride preparation
- Lipoprotien quantification analysis used to directly evaluate HDL-C and LDL-C.

Independent Variables

- Formula-based low-calorie diet (LCD) enriched with:
  - 84 grams per day almonds or
  - Self-selected complex carbohydrates.

Control Variables

- Adjustment made in some statistical models for baseline measurements and all-time points.

Description of Actual Data Sample:

Randomly Assigned

65 [32 almond (59% female), 33 complex CHO(55% female)]

Attrition

13 (eight almond, five complex CHO); 11 work or time conflicts, two returned to lipid-lowering medication

Completed Trial

52 (24 almond, 28 complex CHO)

Demographics

Gender

57% (N=37) females, 43% (N=28) males

Ethnicity

20-22% Caucasian, 4-6% Hispanic, 1-7% African American, 1-4% Asian

Age

53±2 (almond), 57±2 (complex CHO)

Baseline Anthropometrics

	Almond (N=32)	Complex CHO (N=33)
Weight (kg)	113±5	114±5
BMI (kg/m^2)	39±1	37±1
Fat Mass (%)	42±2	43±2
Waist Circumference (cm)	122±5	117±5

Baseline Metabolic Parameters

	Almond (N=32)	Complex CHO (N=33)
Systolic BP (mmHg)	145±4	138±3
Diastolic BP (mmHg)	77±2	78±2
TC (mg/dL)	198±8	216±7
LDL-C (mg/dL)	99±5	108±5
HDL-C (mg/dL)	33±2	33±2
Tg (mg/dL)	180±19	193±16

Note. No significance in baseline demographic, anthropometric or metabolic characteristics were found between groups following randomization.

Summary of Results:

Intervention Compliance

Authors report groups were equally compliant

Changes in Lipid Parameters

(least-squares mean ± s.e.)

	Almond (N=32)				Complex CHO (N=33)			
	Week zero	Week 24	P	Percentage Change	Week zero	Week 24	P	Percentage Change
TC	198±7	173±8	**	-13	216±8	197±8	**	-9
LDL-C	99±5	84±5	***	-15	108±5	97±5	***	-10
HDL-C	33±2	31±2	ns	-6[a]	33±2	38±2	*	+15

LDL-C: HDL:C	3.1±0.2	2.8±0.2	**	-10	3.5±0.2	2.7±0.2	**	-23
Tg	180±17	128±18	***	-29	193±17	141±17	***	-27

Note. All variables adjusted for baseline values in the models
[a]Statistically significant difference in change between groups (P<0.05)
*P<0.05, **P<0.01, ***P<0.001 (within-group comparisons)

Other Relevant Findings

Almond group had significantly greater declines in body weight, BMI, waist circumference, fat mass, total body water, and systolic blood pressure compared to complex CHO group. Subjects self-reported evaluation of almond and complex CHO diet acceptability, satiety, palatability, and texture did not differ over time or between groups.

Author Conclusion:

Similar decreases in TC levels were observed in the context of unequal magnitude of weight loss between the two interventions. The almond group experienced a reduction in LDL-C from baseline by 15% compared to a 10% reduction in the complex CHO group. Although HDL-C did not increase in the almond group, the LDL-C to HDL-C ratio decreased equivalently in both groups.

In light of the wide range of self-selected glycemic index foods, were are unable to explain the rise in HDL-C in the complex CHO group. The difference in HDL-C between groups may be partially attributed to the difference in daily fiber intake (almond: 20g; complex CHO: 32g).

This study demonstrates the use of almonds in the context of a formula-based LCD is a feasible option for consideration and has a potential role in the public health implications of obesity.

Reviewer Comments:

No objective assessment of markers of dietary change (e.g., MUFAs).

Small sample sizes did not permit gender and ethnic or race comparisons.

Subjects were overweight or obese and entering a clinical weight loss program, limiting generalizability to the normal weight population with abnormal lipid profiles.

No control group used.

The almond intervention was embedded within a clinical weight loss program (Diabetes and Cardiovascular Risk Reduction Program) with a formula based low-calorie diet protocol. It is unclear if similar results could be achieved consuming almonds in the same dose within a different context.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes

2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	No
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes

4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes

7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	No
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	No
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	No
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	No